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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 5

<i>Complete if Known</i>	
Application Number	10/618,133
Filing Date	07/11/2003
First Named Inventor	Lixiong Li
Group Art Unit	
Examiner Name	
Attorney Docket Number	ARA-US-P1

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
WS	A	6,585,890	B2	Li et al.	07/01/2003	Entire Patent
WS	B	6,485,649	B1	Terava et al.	11/26/2002	Entire Patent
WS	C	6,406,273	B2	Wong	06/18/2002	Entire Patent
WS	D	6,247,903	B1	Wong	06/19/2001	Entire Patent
WS	E	6,167,951	B1	Couch et al.	01/02/2001	Entire Patent
WS	F	6,094,523		Zelina et al.	07/25/2000	Entire Patent
WS	G	6,086,822		Trinidad	07/11/2000	Entire Patent
WS	H	6,030,436		Barclay	02/29/2000	Entire Patent
WS	I	5,849,958		Naperkowski et al.	09/07/1999	Entire Patent
WS	J	5,928,481		Briggs	07/27/1999	Entire Patent
WS	K	5,917,022		Davies	06/29/1999	Entire Patent
WS	L	5,880,438		Pamini et al.	03/09/1999	Entire Patent
WS	M	5,851,293		Lane et al.	12/22/1998	Entire Patent
WS	N	5,717,303		Engel	02/10/1998	Entire Patent
WS	O	5,498,409		Hirayama et al.	03/12/1996	Entire Patent
WS	P	5,401,499		Hirayama et al.	03/26/1995	Entire Patent
WS	Q	5,401,421		Blum	03/26/1995	Entire Patent
WS	R	5,279,821		Hirayama et al.	01/18/1994	Entire Patent
WS	S	5,242,595		Morgart et al.	09/07/1993	Entire Patent
WS	T	5,202,246		Kruse et al.	04/13/1993	Entire Patent

FOREIGN PATENT DOCUMENTS

Examiner Signature	M. Sawyer	Date Considered	7-31-05
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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				Group Art Unit	
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Sheet	2	of	5	Attorney Docket Number	ARA-US-P1

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		Number	Kind Code ² (if known)			
MG	U	5,188,020		Rockefeller et al.	02/16/1993	Entire Patent
MG	V	5,168,123		Agui et al.	11/24/1992	Entire Patent
MG	w	5,104,546		Filson et al.	04/14/1992	Entire Patent
MG	X	5,032,265		Jha et al.	07/16/1991	Entire Patent
MG	Y	5,026,258		Mosley	06/25/1991	Entire Patent
MG	Z	5,021,391		Agui et al.	06/04/1991	Entire Patent
MG	AA	4,958,858		Zajac	09/25/1990	Entire Patent
MG	BB	4,935,150		Iida et al.	06/19/1990	Entire Patent
MG	CC	4,913,827		Nebel	04/03/1990	Entire Patent
MG	DD	4,909,842		Sato et al.	03/20/1990	Entire Patent
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MG	GG	4,858,843		Vavra et al.	08/22/1989	Entire Patent
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MG	II	4,772,390		Kawai et al.	09/20/1988	Entire Patent
MG	JJ	4,759,909		Joslyn	07/26/1988	Entire Patent
MG	KK	4,752,389		Burrows	06/21/1988	Entire Patent
MG	LL	4,673,733		Chandra et al.	06/16/1987	Entire Patent
MG	MM	4,648,978		Makinen et al.	03/10/1987	Entire Patent
MG	NN	4,610,780		Reti et al.	09/09/1986	Entire Patent

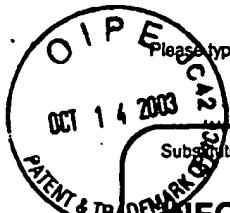
FOREIGN PATENT DOCUMENTS

Examiner Signature	M. Szwarc	Date Considered	7-31-05
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Subpart 1 for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 5

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Application Number	10/618133
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				First Named Inventor	Lixiong Li
				Group Art Unit	
				Examiner Name	
Sheet	4	of	5	Attorney Docket Number	ARA-US-P1

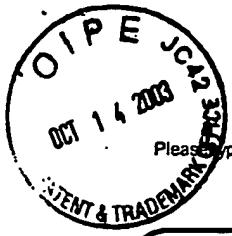
OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
ML	KKK	W. DICKINSON BURROWS and JAMES H. NELSON, IV Fluidmakers: Preparation of Sterile Water for Injection in a Field Setting, Journal of Parenteral Science & Technology, May-June 1993, pp. 124-129, Vol. 47 No. 3		/
ML	LLL	ANDREW W. COLLENTRO, Pharmaceuticals - Practical Microbial Control Techniques for Pharmaceutical Water Purification Systems, Ultrapure Water, March 2002, pp. 53-60		/
ML	MMM	KIYOSHI TSUJI and SUSAN HARRISON, Dry-Heat Destruction of Lipopolysaccharide: Dry-Heat Destruction Kinetics, Appl. Environ. Microb., Nov. 1978, pp. 710-714, Vol. 36 No. 5		/
ML	NNN	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Heat Exchangers to Avoid Contamination, Inspection Technical Guide (ITG) No. 34, July 31, 1979, pp. 1-3, at www.fda.gov/ora/inspect_ref/itg/itg34.html (last visited March 29, 1999)		/
ML	OOO	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Pyrogens, Still a Danger, Inspection Technical Guide No. 32, January 12, 1979, pp. 1-3, at www.fda.gov/ora/inspect_ref/itg/itg32.html (last visited March 29, 1999)		/
ML	PPP	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), Guide to Inspections of High Purity Water Systems, pp. 1-9, at www.fda.gov/ora/inspect_ref/igs/high.html (last visited March 24, 1999)		/
ML	QQQ	KIYOSHI TSUJI and A.R. LEWIS, Dry-Heat Destruction of Lipopolysaccharide: Mathematical Approach to Process Evaluation, Appl. Environ. Microb., Nov. 1978, pp. 715-719, Vol. 36 No. 5		/
ML	RRR	HANS TRAEGER, Pharmaceuticals - The Presence of Bacteria, Endotoxins, and Biofilms in Pharmaceutical Water, Ultrapure Water, March 2003, pp. 17-22		/
ML	SSS	ALEX KONOPKA, Pharmaceuticals - Current Issues and System Design Considerations Affecting Pharmaceutical Water Systems, Ultrapure Water, March 2002, pp. 22-30		/
ML	TTT	DAVID H. PAUL, Back to Basics - The Combining of Reverse Osmosis and Ion Exchange, Ultrapure Water, July/August 2002, pp. 38-40		/
ML	UUU	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) ITG Subject: Bacterial Endotoxins/Pyrogens, Inspection Technical Guide (ITG) No. 40, March 20, 1985, pp. 1-10, at www.fda.gov/ora/inspect_ref/itg/itg40.html (last visited March 24, 1999)		/

Examiner Signature	M. Scwartz	Date Considered	7-31-05
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				Examiner Name	
Sheet	5	of	5	Attorney Docket Number	ARA-US-P1

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
MS	VVV	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Water for Pharmaceutical Use, Inspection Technical Guide (ITG) No. 46, December 31, 1986, pp. 1-4, at www.fda.gov/ora/inspect_ref/itg/itg46.html (last visited October 9, 2003)			/
MS	WWW	EUROPEAN PATENT OFFICE Abstract - Pyrogen Adsorbent and Removal of Pyrogen Using the Same, JP 4-114661, April 15, 1992			/
MS	XXX	EUROPEAN PATENT OFFICE Abstract - Removal of Pyrogen From Resin Carrier, JP 1-203046, August 15, 1989			/
MS	YYY	EUROPEAN PATENT OFFICE Abstract - Removal of Pyrogen From Aqueous Solution, JP 59-112888, June 29, 1984			/
MS	ZZZ	EUROPEAN PATENT OFFICE Abstract - Removal of Pyrogen in Water, JP 57- 171403, October 22, 1982			/

Examiner Signature	M. Survey	Date Considered	7-31-05
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